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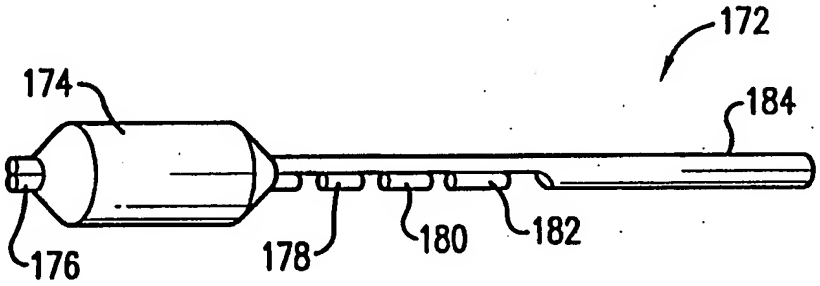

(57) Abstract

The present invention preferably includes a balloon catheter for use with a guidewire. The catheter has a body with a balloon located thereon, preferably at the distal end. A lumen within the catheter body communicates with the interior of the balloon which can be inflated by known methods with saline solution. A series of sleeve members of predetermined lengths and sizes are coupled to and positioned along the length of the catheter body. One or more of the sleeve members can span the length of the balloon. Each sleeve member has a passageway and both an exit and entry port so that the guidewire can pass therethrough. Instead of a balloon, the catheter can include a device member that forms a chamber which can store medicine until discharged at the desired site within the blood vessel. Apertures or pores on the catheter body allow for the perfusion of blood or the delivery of medicine to the site of the blood vessel. A method of operation is also disclosed.

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GUIDING ELEMENT FOR BALLOON CATHETERS OR THE LIKE AND METHOD OF USE

FIELD OF THE INVENTION

The present invention is directed to catheters for delivering balloons, drugs, stents, and other devices or agents into the arterial or venal systems of the human body. In particular, this invention relates to catheters that provide a quick, efficient and rapid exchange capability for the delivery of an angioplasty balloon into the arterial vessels of the human heart.

BACKGROUND ART

The human body includes arterial and venous conduits which run throughout various sections of the human body. These conduits conduct blood into and from the heart which maintain the circulation that helps to sustain the metabolic events in the body. The vessels undergo biological, physiological and mechanical changes depending on the body metabolism which determine the functionality of the wall of the artery.

Sometimes the wall of an artery becomes occluded due to deposits of fatty tissues which in turn form plaque on the walls of the artery. These plaques then have to removed to restore the normal function of the artery. One known mechanism of removing the plaque is to compress the plaque against the wall of the artery using a balloon catheter. This procedure is called Percutaneous (under the skin) Transluminal (under x-ray guidance) Coronary (region of intervention) Angioplasty (plaque compression) or PTCA.

For a PTCA procedure to be accomplished, a balloon catheter and a guidewire along with a guiding catheter are typically required. The guiding catheter is normally introduced in a groin artery and pushed upwards towards the aorta until it reaches the mouth of the coronary artery. Once the guiding catheter is placed at the opening of the coronary artery, a highly floppy wire is introduced into the

guiding catheter such that the wire crosses the mouth of the guiding catheter and goes into the coronary artery. It then has to reach the site of the lesion (plaque) which is usually a very tortuous route and the operator (the cardiologist) has to struggle to reach the guidewire in place. Once a guidewire has crossed the lesion, it is then pushed distally to the lesion so that it remains at a safe place. This is to ensure that the wire does not slip out of the lesion.

A catheter which has a balloon at one end and a shaft at the other end is usually introduced into the lesion on top of the guidewire. Although the mechanism of introduction and the design of the catheter that facilitate the mechanism have been improved by known catheters, they still leave room for improvement.

Several designs of balloon catheters are disclosed in various U.S. patents that facilitate insertion into the artery using a guidewire as an intermediate tool. The way in which the balloon travels on top of the guidewire and the length of the catheter that travels on top of the guidewire is the subject of known devices such as those shown and described in U.S. Patents Nos. 5,620,417; 5,607,406; 5,607,394; 5,598,844; 5,549,556; 5,545,134; 5,531,690; 5,514,092; 5,077,311; 5,501,227; 5,489,271; 5,472,425; 5,468,225; 5,460,185; 5,458,613; 5,443,457; 5,413,560; 5,413,559; 5,409,097; 5,387,226; 5,383,853; 5,380,283; 5,357,978; 5,336,184; 5,334,147; 5,195,978; 5,170,286; 4,748,982; 4,762,129; and 5,626,600, all of which are incorporated herein in their entirety.

While each one of these above-listed patents describe and illustrate several ways of approaching the traverse mechanism, all of them essentially assume the following; (1) the catheter has proximal and distal ends; (2) there is a balloon mounted on the distal end; (3) the proximal end has a shaft; (4) the interior of the balloon is in communication with a lumen; (5) there is another sleeve that either extends towards the entire length of the catheter or runs at a fixed distance from the distal end of the catheter; (6) the sleeve

if it does not run the entire length of the catheter extends up to a predetermined distance from the balloon up to the midsection of 1/3 of the entire catheter length or sometimes shorter; (7) the portion of the sleeve is called the flexible portion, while the proximal portion is either a hallow tube or an elliptical structure which provides for pushability of the catheter; (8) the sleeve has one opening at the proximal side of the balloon through which a guidewire can be inserted and it comes out through the center of the balloon--this is commercially known as the rapid exchange or the monorail concept; (9) in instances where the sleeve extends along the entire length of the balloon the wire extends inside the sleeve from the distal to the proximal end of the catheter through the balloon--this is called the over the wire concept.

In the devices of the above patents, regardless of whether the catheter is over the wire or monorail, the guidewire has one entry point and one exit point and the regions between the entry and exit are imbedded in the catheter sleeve or the catheter shaft.

However, the catheters of the above patents have some serious disadvantages in lesions that are completely occluded or in lesions that have severe tortuosity. In lesions that have complex distal diseases the catheter has to traverse multiple bifurcations in order to reach the site of lesion. In case of the above described known catheters, the operator or the cardiologist forces the body of the catheter on top of the wire using an external force. This force then transmits from the catheter body to the surface of the wire. When the wire is held with a counteractive force, the force against the catheter becomes greater and a law of physics comes into play, the object with the greatest force moves forward.

In balloon angioplasty, it is desired to design a catheter which pushes on top of a wire with a minimum force. In order to achieve this, catheters with very low profiles are sought. These low profiles enable easy slippage on top

of the wire. Sometimes the wires are also coated with a lubricous coating to enable ease of passage of the catheter.

In numerous instances, the operator is unable to cross a lesion with a rapid exchange catheter. He then switches over to an over the wire design or vice versa when the operator cannot transmit the necessary force for the balloon catheter to traverse the lesion.

In general rapid exchange catheter designs are preferred because there is only about 1/3 of the catheter body that is imbedded in the guidewire and hence the force required for the catheter to travel is less. In the case of total occlusions, over the wire designs are preferred as the catheter. If the catheter is being pushed through a very hard plaque or a totally occluded artery, the maximum force from the proximal end of the catheter has been delivered to the distal end.

The force delivered at the proximal end by the operator relates to the force of balloon moving forward toward the lesion. There are forces lost between the proximal end to the distal end of the catheter and this happens due to the tortuosity of the lesions, length of the shaft of the catheter and also lesion morphology.

Prior art inventions are easily understood if we draw a very simple analogy between the catheter and the guidewire. Assume the guidewire is the track of the train, and the catheter is the train. In the rapid exchange design, the train has one pair of small wheels that are the distal 1/3 of the catheter of the length of the sleeve. In the case of an over the wire design, the train has one pair of long wheels from the distal end of the catheter to the proximal end.

SUMMARY OF THE INVENTION

The present invention is directed to a catheter comprising body member having a lumen; balloon member disposed on the body member and communicating with the lumen; and plurality of sleeve members disposed on the body member, each sleeve member having a passageway therethrough.

In one preferred embodiment, at least one of the sleeve members is disposed in a distal region of the elongated member. The at least one of the sleeve members can be disposed adjacent the balloon member and can have a length less than that of the balloon member. The at least one of the sleeve members can be disposed within the balloon member.

According to a catheter of the present invention, at least one of the sleeve members can be disposed adjacent the balloon member and have a length greater than that of the balloon member. The at least one of the sleeve members extends through the balloon member.

In another preferred embodiment, the at least one of the sleeve members can be disposed generally centrally of the balloon member.

In alternative embodiments, the at least one of the members can be disposed generally eccentrically of the balloon member, or generally outside of the balloon member, or proximally of the balloon member. The remaining sleeve members can be equally sized and equally spaced along the catheter body. Alternatively, the remaining sleeve members can be differently sized and differently spaced along the catheter body. Preferably there are two or three remaining sleeve members.

The present invention is also directed to an angioplasty catheter comprising elongated body member having a lumen which includes an opening adjacent its distal end and at least one opening adjacent its proximal end; balloon member sealingly disposed on the elongated member adjacent its distal end, the elongated member having at least one opening communicating with the interior of the balloon and the lumen within the elongated body member; and plurality of sleeve members disposed on the elongated member, each sleeve member having a passageway therethrough.

An angioplasty catheter, according to the present invention, can also comprise guidewire dimensioned and configured for passing through the passageway of the sleeve members.

The present invention is also directed to a catheter comprising body member having a lumen; and plurality of sleeve members disposed on the body member, each sleeve member having a passageway therethrough.

A catheter, according to the present invention, comprises generally rigid body member having a lumen; balloon member disposed on the body member and communicating with said lumen; and plurality of generally flexible sleeve members disposed on the body member, each sleeve member having a passageway therethrough.

The present invention also is directed to a catheter which comprises body member having a lumen; device member disposed on the body member; and plurality of sleeve members disposed on the body member, each sleeve member having a passageway therethrough. The device member can be a stent or a container having a chamber for containing a drug.

Also, the present invention is directed to a method of using a catheter comprising providing a catheter including body member having a lumen; balloon member disposed on the body member and communicating with the lumen; and plurality of sleeve members disposed on the body member, each sleeve member having a passageway therethrough; selectively passing a guidewire through the passageways of the sleeve members, the guidewire being disposed in a body cavity, so as to position the catheter at a desired location within the body cavity; and selectively inflating the balloon and withdrawing the catheter from within the body cavity.

The present invention is also directed to a method of using a catheter comprising providing a catheter including body member having a lumen; device member disposed on the body member; and plurality of sleeve members disposed on the body member, each sleeve member having a passageway therethrough; selectively passing a guidewire through the passageways of the sleeve members, the guidewire being disposed in a body cavity, so as to position the catheter at a desired location within the body cavity; and selectively operating the device member within the body cavity.

According to one preferred embodiment wherein the device member comprises a container having a chamber containing a drug, the method further comprises releasing the drug from the chamber. Alternatively, wherein the device member comprises a stent, the method further comprises releasing the stent within the body cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in detail below with reference to the drawings wherein:

FIG. 1A is a cross-sectional view of a balloon catheter according to the prior art taken along the midsection of the balloon, wherein the balloon lumen is in the center and the guidewire lumen is eccentric to the balloon but in the shaft of the catheter.

FIG. 1B is a cross-sectional view of a balloon catheter according to the prior art wherein the balloon lumen is in the center and the guidewire lumen is eccentric to the shaft.

FIG. 1C is a cross-sectional view of a bi-lumen catheter according to the prior art wherein the guidewire lumen and the balloon lumen are concentric to the shaft of the catheter.

FIG. 1D is a cross-sectional view of the balloon catheter according to the prior art wherein the guidewire lumen and the balloon lumen are in a symmetrical axis to each other.

FIG. 2A is a side view of a balloon catheter according to the prior art wherein the guidewire sleeve exits proximally out of the balloon about 2/3 the length of the catheter.

FIG. 2B is a side view of a balloon catheter according to the prior art wherein the guidewire sleeve exits at the proximal tip of the balloon.

FIG. 2C is a side view of a balloon catheter according to the prior art wherein the guidewire sleeve exits adjacent but prior to the proximal end of the catheter.

FIG. 2D is a side view of another embodiment of a balloon catheter according to the prior art wherein the guidewire sleeve exits at the proximal end of the catheter.

FIG. 3A is a side view of an embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of four spaced apart sleeve members and wherein the sleeve member through the balloon is the longest.

FIG. 3B is a side view of another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of four spaced apart sleeve members wherein the guidewires lumen is eccentric to the balloon lumen and exits proximal to the balloon.

FIG. 3C is a side view of an yet another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of four spaced apart sleeve members which are more closely spaced than the sleeve members in FIG. 3A or 3B.

FIG. 3D is a side view of an still another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of three spaced apart sleeve members and wherein the sleeve member through the balloon is the longest.

FIG. 3E is a side view of an still yet another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of five different sized and differently spaced apart guidewire sleeve members.

FIG. 4A is a side view of an embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of three spaced apart sleeve lumens located along and extending beyond the ends of the balloon and wherein the guidewire lumen is eccentric to the balloon.

FIG. 4B is a side view of an embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of three spaced apart sleeve

lumens and wherein two sleeve lumens are positioned distally of the balloon and the remaining sleeve lumen is positioned in the region of the balloon and wherein the guidewire lumen is eccentric to the balloon.

FIG. 4C is a side view of an yet another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of three spaced apart sleeve lumens positioned distally of the balloon and wherein the guidewire lumen is eccentric to the balloon.

FIG. 4D is a side view of still yet another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of three spaced apart sleeve lumens positioned proximally of the balloon.

FIG. 5 is a side view of an embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of four spaced apart sleeve members and wherein the sleeve member through the balloon is the longest.

FIG. 6 is a side view of a generally rigid tube for use with the balloon catheter of FIG. 6.

FIG. 7 is a side view of an yet another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of two spaced apart sleeve members and wherein the balloon is disposed on a flexible sheath which is coupled to the generally rigid tube of FIG. 6 so that the flexible portion is distal and the rigid portion is proximal.

FIG. 8 is a side view of an still another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of two spaced apart sleeve members and the catheter shaft includes proximal and distal apertures for perfusion of blood during angioplasty.

FIG. 9 is a side view of an still yet another embodiment of a balloon catheter according to the present invention wherein the catheter shaft has microporous holes disposed along the shaft for drug delivery.

FIG. 10 is a side view of an yet another embodiment of a balloon catheter according to the present invention wherein the guidewire sleeve is formed of two spaced apart sleeve lumens and wherein the balloon carries a stent.

FIG. 11 is a side view of the balloon catheter of FIG. 10 having different sized sleeve members and further including a sheath on the stent for removal and inflation.

FIG. 12 is a side view of an yet another embodiment of a balloon catheter according to the present invention for use in drug delivery wherein the drug delivery device is in a closed position.

FIG. 13 is a side view of the balloon catheter of FIG. 12 but wherein the drug delivery device is in an open position for delivcery of the drug.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the description which follows, any reference to direction or orientation is intended primarily and solely for purposes of illustration and is not intended in any way as a limitation to the scope of the present invention. Also, the particular embodiments described herein, although being preferred, are not to be considered as limiting of the present invention.

An invention is hereby described which applies the laws of physics and also the general principle of train on a track. A train moves on a track with multiple wheels which are positioned at equal distances form the engine. The present invention applies this principle to a catheter by having multiple entry points and exit points of a catheter body for the passage of a guidewire.

From physics it is known that the force required to push an object on top of another depends on the surface area of coverage and the nature of the radial coverage that enables a longitudinal force to be transmitted while the object is being pushed on top of the other object.

Various known balloon catheter configurations are shown in FIGS. 1A-1D and FIGS. 2A-2D. In FIG. 1A, a balloon 10 is

shown with an internally and centrally positioned balloon lumen 12 and a guidewire lumen 14 which is in the shaft of the catheter but eccentric to the balloon 10. In the catheter shown in FIG. 1B, the balloon lumen 16 is centrally located within the balloon 20 and the guidewire lumen 18 which is eccentric to the shaft and the balloon 20. The catheter shown in FIG. 1C has a balloon 22 with internal guidewire lumen 24 and surrounding balloon lumen 26. Both guidewire lumen 24 and balloon lumen 26 are concentric to the shaft of the catheter. In FIG. 1D, the guidewire lumen 30 and balloon lumen 34 are positioned within balloon 36 so that the balloon lumen 34 is centrally positioned and the guidewire lumen 30 is outside of the balloon lumen 34.

In reference to FIG. 2A, a known catheter 38 includes a catheter body 40 with a distally positioned balloon 42. A guidewire lumen 44 for a guidewire (not shown) extends from the distal end of the catheter but exits before the full length of the catheter 38. In the catheter 46 of FIG. 2B, the guidewire lumen 48 extends through the balloon 50 and exits at the proximal end of the balloon 50. In another known catheter 52 shown in FIG. 2C, the guidewire lumen 54 extends through the balloon 56 and extends closely to the proximal end of the catheter body 58. As shown in FIG. 2D, the catheter 60 has a catheter body 62, a balloon 64 and a guidewire lumen that extends the length of the balloon 64.

Referring to FIG. 3A, a balloon catheter 100 according to the present invention has a catheter body 102 and a distal balloon 104. Coupled to the catheter body 102 are four sleeve members including the longest member 106 that spans the balloon 104. The other three sleeve members 108 are equal in size and spaced apart from each other and sleeve member 106. Each sleeve member 106 and 108 has an entry port 110 which is located at the most distal end of the sleeve member and an exit port 112 located at the proximal end of the respective sleeve member. Thus the sleeve members provide multiple points of entry for the guidewire (not shown) and corresponding multiple points of exit for the

guidewire. The exit port 112 for the largest sleeve member 106 is proximal to the proximal end of the balloon 104 either concentric or eccentric to the balloon 104. Alternatively, the other ports of exit 112 can be located at various distances along the length of the catheter 100. These ports of entry and exit can be located at various predetermined locations. Various desired predetermined configurations of displacements of the sleeve members 106 and 108 can be utilized as well as various lengths of the different sleeves. These points run along the entire length of the catheter or can run only in the distal part of the catheter.

Depending on the lesion morphology and also the tortuosity of the lesion, the length of the catheter which runs on the guidewire can be selected.

In one preferred embodiment, a catheter can have four points or five points of entry and five points of exit. In an alternative embodiment, the catheter can have seven points of entry and seven points of exit.

Depending on the length of the coverage of each, the exposed segments of the catheter between the sleeve members act as wheels. Hence the catheter of the present invention provides multiple wheels that guide the catheter.

The first point of entry is ideally located at the tip of the balloon and can run concentric to the balloon axis or can run eccentric to the balloon axis, the first point of exit is located just after the balloon or a short distance proximal to it. The second point of entry is located at a distance greater than the first point of entry and subsequent exit at second pint. The distance between the first point of exit and the second point of entry is the exposed part of the wire in the body of the catheter. This exposed part of the wire is called the "wire segment". The distance between the second point of entry and the second point of exit is called the "catheter segment", the wire segment and the catheter segment can alternate along the entire length of the catheter or only on the distal 1/3 of the catheter.

A catheter is also described wherein the first point of entry is located distal to the location of the balloon such that the wire does not pass inside the lumen of the balloon. In such a case the catheter shaft that has "wire segments" and "catheter segments" is taken at the site of the lesion, the wire pulled back such that it is proximal to the balloon and the balloon is then dilated at the site of the lesion.

Referring to FIG. 3B, the catheter 114, similar to that shown in FIG. 3A, has a balloon 116 and four sleeve members 118 and 120 which are equally spaced apart. Sleeve member 118 is the longest and spans the balloon 116. Unlike catheter 100 wherein sleeve member 106 is a separate tubular structure coupled to catheter body 102, sleeve member 118 in catheter 114 can be formed as part of the catheter body 122. In the alternative embodiment of FIG. 3C, the catheter 124 has four sleeve members 126 and 128 that are more closely spaced than in FIGS. 3B and 3C.

In yet another alternative embodiment, catheter 130 in FIG. 3D includes three sleeve member 132 and 134 which are spaced at different intervals along the catheter body 136. Still another embodiment 138 shown in FIG. 3E has five different spaced and different sized sleeve members 140, 142, 143, 144 and 145. The catheter 138 has a catheter body 146 that at its proximal end has a Y-lumen configuration 148.

Turning to the catheter embodiment 150 shown in FIG. 4A, a catheter body 152 has a balloon structure 154 (shown schematically) at the distal end of the catheter 150. Three equally sized and spaced sleeve members 156 are positioned distally and span the length of the half balloon 154. In the alternative embodiments 158 and 160 illustrated schematically in FIGS. 4B and 4C, the balloon 154 is located on the catheter body 152 closer to the proximal end of the catheters 158 and 160. In the embodiment 162 of FIG. 4D, the balloon 164 is positioned distally of the sleeve members 166 that receive guidewire 168 that passes through the passageways of each sleeve member 166. In the exemplary embodiment of FIG. 4D, the guidewire 168 has a curled distal end 170 but

straight configurations can also be employed with the catheters of the present invention.

Referring to FIG. 5, a catheter 172 includes a balloon 174 and four sleeve members 176, 178, 180 and 182 which are coupled to a shaft 184 that has a larger diameter proximal end portion. FIGS. 6 and 7 illustrate two parts of balloon catheter 186 that can be combined to form the catheter. The structure of FIG. 6 is a generally rigid tube 188. In FIG. 7, the guidewire sleeve is formed of two separate members 188 and 190 that are connected to a balloon lumen 192 that allows for inflation of balloon 194. The balloon lumen 192 is a generally flexible sheath which can be coupled to the generally rigid tube shown in FIG. 6. After combining the components of catheter 186, the flexible portion is distal and the rigid portion is proximal.

In the embodiment of FIG. 8, the balloon catheter 196 has a guidewire sleeve that is formed of two spaced apart sleeve members 198 and 200. Included on the catheter shaft 202 are proximal and distal apertures 204 that allow for the perfusion of blood during angioplasty. In the catheter 206 shown in FIG. 9, microporous holes 208 are provided along the length of the catheter shaft 210. Guidewire lumens (not shown) according the present invention can be attached to the shaft 210 at various locations along the catheter body.

In general, each sleeve member of the various embodiments disclosed and described herein has an entry port 110 and an exit port 112 as shown and discussed in connection with the catheter 100 of FIG. 3A. Also, each sleeve member has a passageway to accommodate the passage of the guidewire. The embodiments herein demonstrate that various sized and spaced sleeve members can be employed to allow for passage of a guidewire. Also, the guidewire lumens can be attached or coupled to the catheter shaft by various known methods of attachment. Alternatively, the guidewire lumens can be formed integrally with the catheter body.

The invention also covers other interventional devices apart from the balloon to include stents, mounted on balloons

or otherwise, drug delivery devices where the media can be delivered distal to the balloon or proximal to the balloon. Thus the catheter of the present invention allows for improved pushability and control over that available with known catheters. The balloon can be made of compliant, semi-compliant or a non-compliant polymeric material, or a combination of a polymeric material. The body member can be made of metal, plastic or a combination of both. The sleeve member is preferably made of plastic, polymeric material. In use, the balloon can be inflated with saline or a contrast fluid as is known by those skilled in the art.

In the embodiment illustrated in FIG. 10, a balloon catheter 210 includes a balloon 212 disposed on a catheter shaft or balloon lumen 214 which has guidewire lumens 216 and 218. A stent 220 is positioned on and carried by the balloon 212. After the balloon 212 is located at the preferred or desired site within a blood vessel, the stent can be released, the balloon deflated and the catheter 210 removed. In the embodiment shown in FIG. 11, the catheter 222 also includes a sheath on the stent for removal and inflation. Different sized and positioned guidewire lumens 224 and 226 can be used with balloon 228. Drug delivery catheters 230 are shown in FIGS. 12 and 13 which can be used with the guidewire lumens (not shown) of the present invention. In FIG. 12, the catheter 230 is shown as including a catheter shaft 232 with a distally positioned device member 234 which is shown in a closed configuration in FIG. 12 and in an open and drug released configuration in FIG. 13. The device member 234 has a hollow chamber inside for storing a desired drug for delivery to a location within a body cavity such as a blood vessel. Alternatively, the device member 234 can store and delivery other medical devices suitably sized so that they can be carried within device member 234. The drug within device member 234 can be discharged by saline fluid which can be injected into the device member 234 through a suitably provided lumen within catheter shaft 232. Other mechanical release systems can also be employed.

While the present invention has been described and illustrated herein with respect to the preferred embodiments thereof, it should be apparent that various modifications, adaptations and variations may be made utilizing the teachings of the present disclosure without departing from the scope of the invention and are intended to be within the scope of the present invention.

THE CLAIMS

What is claimed is:

1. Catheter comprising:

a. body member having a lumen;

b. balloon member disposed on said body member and communicating with said lumen; and

c. plurality of sleeve members disposed on said body member, each sleeve member having a passageway therethrough.

2. The catheter of claim 1 wherein at least one of said sleeve members is disposed in a distal region of said elongated member.

3. The catheter of claim 2 wherein said at least one of said sleeve members is disposed adjacent said balloon member and has a length less than that of said balloon member.

4. The catheter of claim 3 wherein said at least one of said sleeve members is disposed within said balloon member.

5. The catheter of claim 2 wherein said at least one of said sleeve members is disposed adjacent said balloon member and has a length greater than that of said balloon member.

6. The catheter of claim 5 wherein said at least one of said sleeve members extends through said balloon member.

7. The catheter of claim 2 wherein said at least one of said sleeve members is disposed generally centrally of said balloon member.

8. The catheter of claim 2 wherein said at least one of said sleeve members is disposed generally eccentrically of said balloon member.

9. The catheter of claim 2 wherein said at least one of said sleeve members is disposed generally outside of said balloon member.

10. The catheter of claim 2 wherein said at least one of said sleeve members is disposed proximally of said balloon member.

11. The catheter of claim 2 wherein said remaining sleeve members are equally sized and equally spaced along the catheter body.

12. The catheter of claim 2 wherein said remaining sleeve members are differently sized and differently spaced along the catheter body.

13. The catheter of claim 2 wherein there are three remaining sleeve members.

14. The catheter of claim 2 wherein there are two remaining sleeve members.

15. The catheter of claim 1 wherein said body member has a plurality of apertures on said body member.

16. Angioplasty catheter comprising:

a. elongated body member having a lumen which includes an opening adjacent its distal end and at least one opening adjacent its proximal end;

b. balloon member sealingly disposed on said elongated member adjacent its distal end, said elongated member having at least one opening communicating with the

interior of said balloon and said lumen within said elongated body member; and

c. plurality of sleeve members disposed on said elongated member, each sleeve member having a passageway therethrough.

17. The catheter of claim 16 wherein at least one of said sleeve members is disposed in a distal region of said elongated member.

18. The catheter of claim 17 wherein said at least one of said sleeve members is disposed adjacent said balloon member and has a length less than that of said balloon member.

19. The catheter of claim 18 wherein said at least one of said sleeve members is disposed within said balloon member.

20. The catheter of claim 17 wherein said at least one of said sleeve members is disposed adjacent said balloon member and has a length greater than that of said balloon member.

21. The catheter of claim 20 wherein said at least one of said sleeve members extends through said balloon member.

22. The catheter of claim 16 wherein said at least one of said sleeve members is disposed generally centrally of said balloon member.

23. The catheter of claim 16 wherein said at least one of said sleeve members is disposed generally eccentrically of said balloon member.

24. The catheter of claim 16 wherein said at least one of said sleeve members is disposed generally outside of said balloon member.

25. The catheter of claim 16 wherein said at least one of said sleeve members is disposed proximally of said balloon member.

26. The catheter of claim 16 wherein said remaining sleeve members are equally sized and equally spaced along the catheter body.

27. The catheter of claim 16 wherein said remaining sleeve members are differently sized and differently spaced along the catheter body.

28. The catheter of claim 16 wherein there are three remaining sleeve members.

29. The catheter of claim 16 wherein there are two remaining sleeve members.

30. The catheter of claim 16 wherein said body member has a plurality of apertures on said body member.

31. Angioplasty catheter comprising:

a. elongated body member having a lumen and having an opening at its proximal end and at least one opening adjacent its distal end;

b. elongated balloon member sealingly disposed on said elongated body member adjacent its distal end, said elongated body member having at least one opening communicating with the interior of said balloon and said lumen within said elongated body member;

c. plurality of sleeve members disposed on said elongated member, each sleeve member having a passageway therethrough; and

d. guidewire dimensioned and configured for passing through the passageway of said sleeve members.

32. The catheter of claim 31 wherein said body member has a plurality of apertures on said body member.

33. Catheter comprising:

a. body member having a lumen; and

b. plurality of sleeve members disposed on said body member, each sleeve member having a passageway therethrough.

34. Catheter comprising:

a. generally rigid body member having a lumen;

b. balloon member disposed on said body member and communicating with said lumen;

c. plurality of generally flexible sleeve members disposed on said body member, each sleeve member having a passageway therethrough.

35. Catheter comprising:

a. body member having a lumen;

b. device member disposed on said body member; and

c. plurality of sleeve members disposed on said body member, each sleeve member having a passageway therethrough.

36. The catheter of claim 35 wherein said device member is a stent.

37. The catheter of claim 35 wherein said device member comprises a container having a chamber.

38. The catheter of claim 37 wherein said chamber contains a drug.

39. Method of using a catheter comprising:

1. providing a catheter comprising:

a. body member having a lumen;

b. balloon member disposed on said body member and communicating with said lumen; and

c. plurality of sleeve members disposed on said body member, each sleeve member having a passageway therethrough.

2. selectively passing a guidewire through said passageways of said sleeve members, said guidewire being disposed in a body cavity, so as to position said catheter at a desired location within the body cavity; and

3. selectively inflating said balloon and withdrawing said balloon from within the body cavity.

40. Method of using a catheter comprising:

1. providing a catheter comprising:

a. body member having a lumen;

b. device member disposed on said body member; and

c. plurality of sleeve members disposed on said body member, each sleeve member having a passageway therethrough;

2. selectively passing a guidewire through said passageways of said sleeve members, said guidewire being disposed in a body cavity, so as to position said catheter at a desired location within the body cavity; and

3. selectively operating said device member within the body cavity.

41. The method of claim 40 wherein said device member comprises a container having a chamber containing a drug and further comprising releasing said drug from said chamber.

42. The method of claim 40 wherein said device member comprises a stent and further comprising releasing said stent within the body cavity.

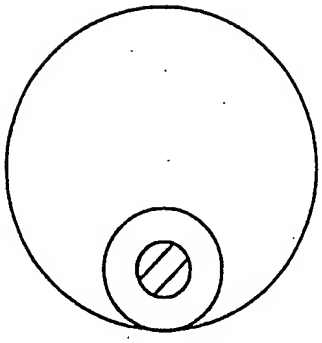

FIG.1A
PRIOR ART

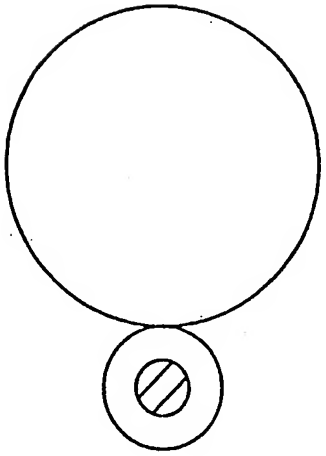

FIG.1B
PRIOR ART

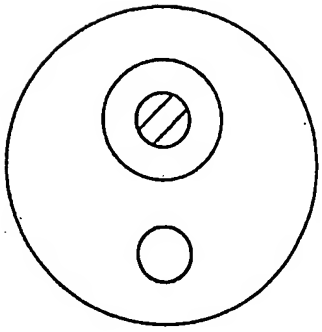

FIG.1C
PRIOR ART

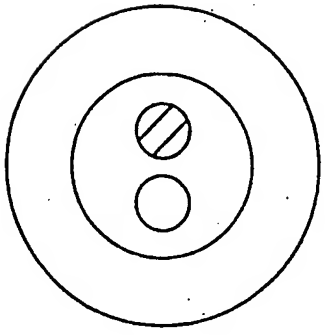

FIG.1D
PRIOR ART

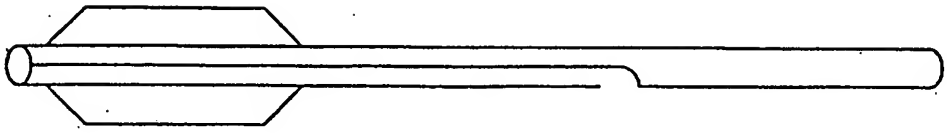

FIG.2A
PRIOR ART

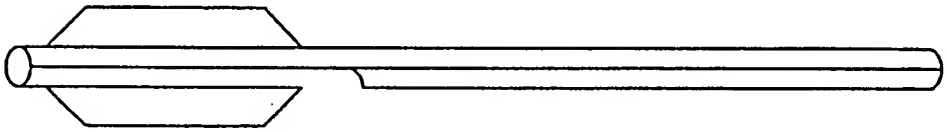

FIG.2B
PRIOR ART

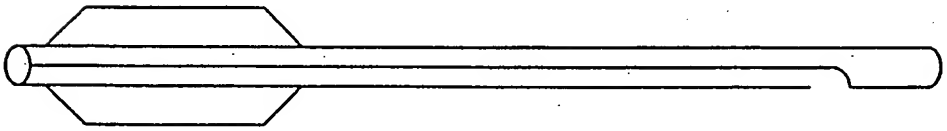

FIG.2C
PRIOR ART

FIG.2D
PRIOR ART

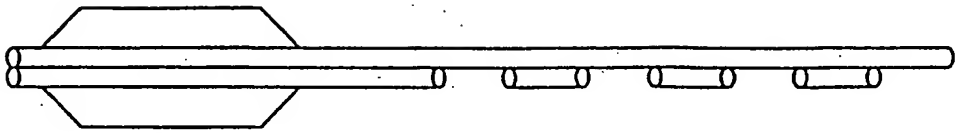

FIG.3A

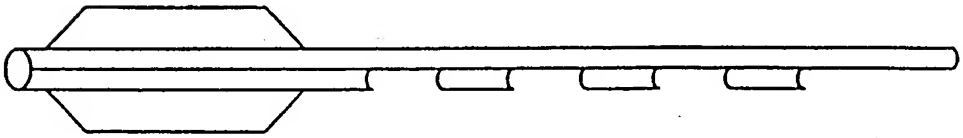

FIG.3B

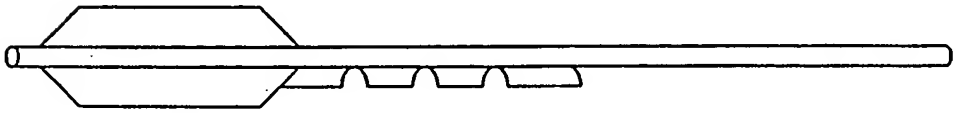

FIG.3C

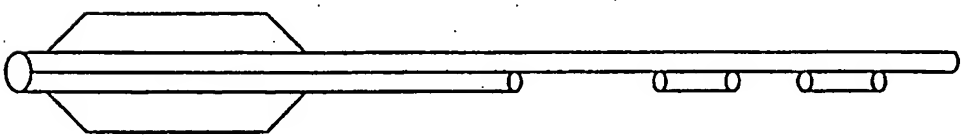

FIG.3D

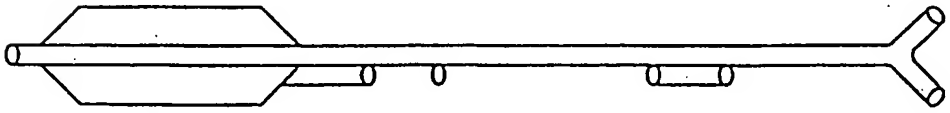

FIG.3E

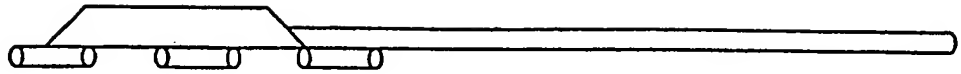

FIG.4A

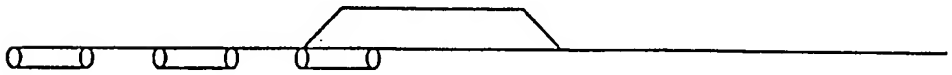

FIG.4B

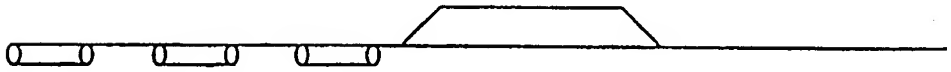

FIG.4C

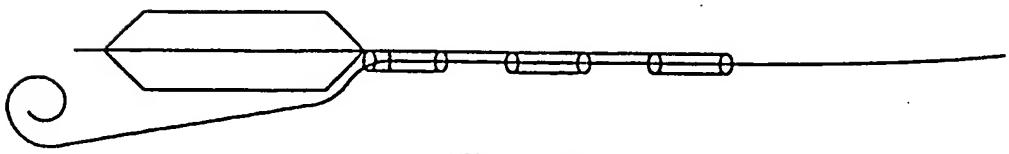

FIG.4D

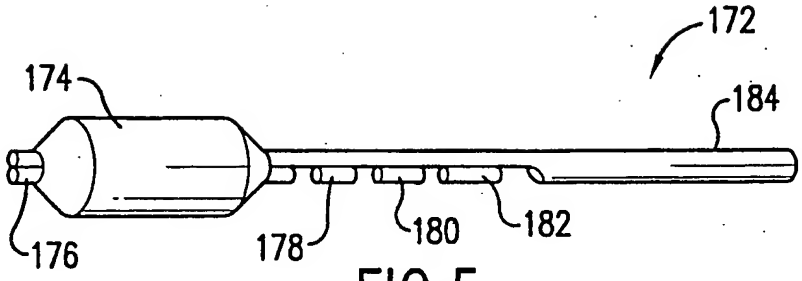

FIG.5

FIG.6

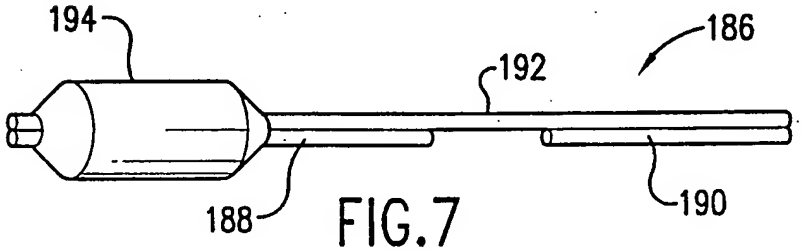

FIG.7

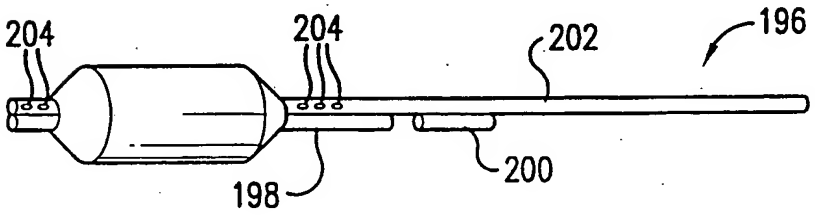

FIG.8

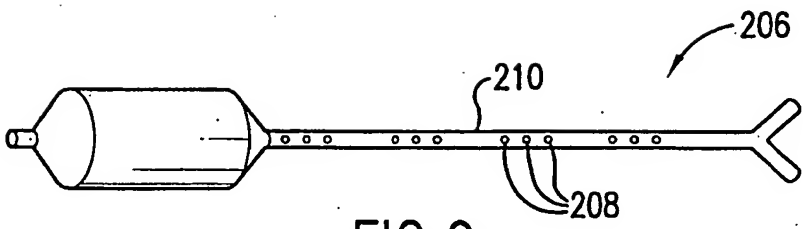

FIG.9

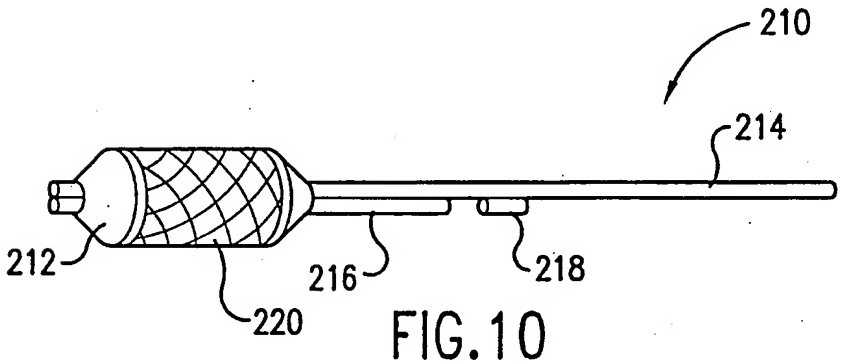

FIG.10

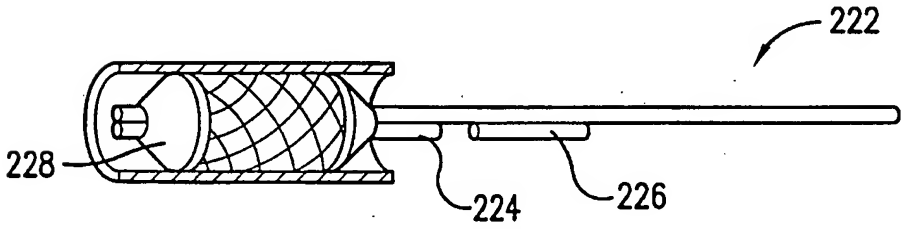

FIG. 11

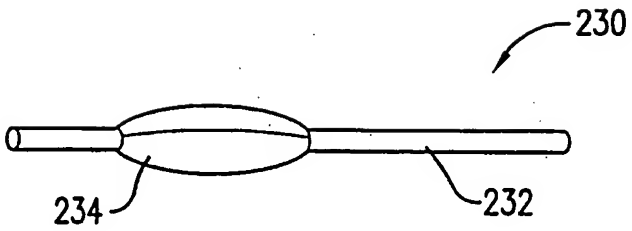

FIG. 12

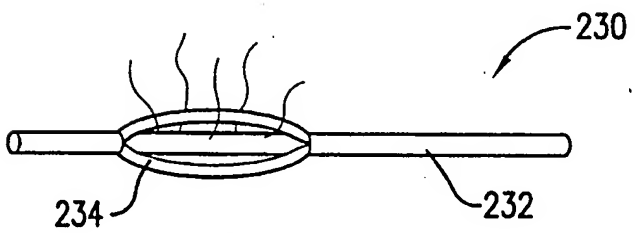

FIG. 13

INTERNATIONAL SEARCH REPORT

Inte. ..ional Application No
PCT/GB 98/02786

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M29/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 267 958 A (LIEBER ET AL.) 7 December 1993 see abstract; claims 1-3; figures 1-7	1-38
A	US 5 443 456 A (GINSBURG ET AL.) 22 August 1995 see abstract; claims 1-4; figures 1-9	1-38
A	US 5 578 009 A (HORZEWSKI ET AL.) 26 November 1996 see abstract; figures 1-3,6,8,9	1-38
A	US 5 645 533 A (BURMEISTER ET AL.) 8 July 1997	
A	US 5 549 553 A (BLAESER ET AL.) 27 August 1996	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 December 1998	10/12/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Michels, N

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 98/02786

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 39-42
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte. ..tional Application No
PCT/GB 98/02786

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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